



3600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662
www.mdtech.com

MAY 31 2002

May 13, 2002

510(k) SUMMARY K021606

APPLICANT: Medical Device Technologies, Inc.
3600 SW 47th Avenue
Gainesville, FL 32608

CONTACT: Karl Swartz
Quality Assurance Manager

TELEPHONE: (352)338-0440
fax (352)338-0662

TRADE NAMES: En-Snare™ Endovascular Snare and Catheter

COMMON NAME: Intravascular snare and catheter

CLASSIFICATION NAME: Percutaneous Catheter, 21 CFR 870.1250

PRODUCT CODE: 78 DQY

PANEL: Cardiovascular

SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Microvena	Amplatz Goose Neck Snare	K970668 and K972511

DESCRIPTION OF DEVICE:

The En-Snare™ Endovascular Snare and Catheter is comprised of stranded nitinol/platinum cables mechanically secured to a nitinol wire inserted into an intravascular catheter and manipulated by use of an external pin vise. The catheter is made from biocompatible FPE that has been used extensively in intravascular catheters.

INDICATIONS FOR USE:

The En-Snare™ Endovascular Snare and Catheter is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access veni-puncture procedure assistance.





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FUNCTIONAL & SAFETY TESTING:

The En-Snare™ Endovascular Snare and Catheter were subjected to capture function, tip deflection, torqueability, tensile strength, flow rate, hub leakage, and stiffness tests. The results of the testing indicated that they are comparable to the predicate device.

TECHNICAL COMPARISON:

The following attributes of the En-Snare™ Endovascular Snare and Catheter were examined and found to be comparable to the predicate device:

CATHETER	SNARE
1. Intended use	1. Intended use
2. French Sizes	2. Sizes
3. Length	3. Length
4. Lumens	4. Distal end configuration
5. Distal end configuration	5. Intended anatomical location of distal end
6. Intended anatomical location of distal end	6. Proximal end configuration
7. Proximal end configuration	7. Materials
8. Materials	8. Labeling
9. Labeling	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Medical Device Technologies, Inc
c/o Mr. N.E. Devine, Jr.
Entela, Inc.
3033 Madison Ave, SE
Grand Rapids, MI 49548

Re: K021606
En-Snare™ Endovascular Snare and Catheter
Regulation Number: 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: 74 MMX
Dated: May 13, 2002
Received: May 16, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);


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labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Number (if known): K021606


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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K021606

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

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MEDICAL DEVICE TECHNOLOGIES INC.



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